



UNITED STATES DEPARTMENT OF COMMERCE

Patent and Trademark Office

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#36

AUG - 5 1993

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fisher's Lane, Room 11-44
Rockville, MD 20857

Re: Reality Female Condom
FDA Docket No. 93E-0268

Dear Mr. Wilson:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 4,976,373 issued December 11, 1990. The application was filed on July 2, 1993, under Title II of Public Law 98 - 417, the Drug Price Competition and Patent Term Restoration Act of 1984.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office on the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 USC § 156 (d)(2)(A).

C. E. Van Horn

Charles E. Van Horn
Patent Policy & Projects Administrator
Office of the Assistant Commissioner for Patents

cc: Paul Grandinetti
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February 16, 1994

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VIA FACSIMILE AND FIRST CLASS MAIL

FEB 22 1994

Mr. Brian J. Malkin
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
FOOD AND DRUG ADMINISTRATION
5600 Fisher's Lane, Room 15-22
Rockville, Maryland 20857

**Re: Reality Female Condom
Patent Term Extension
U.S. Patent No. 4,976,273
FDA Docket No. 93E-0268**

Dear Mr. Malkin:

Chartex International Plc provides the following information in response to your inquiry regarding the early U.K. studies of the Reality/Femidom brand female condom.

The original U.K. clinical studies occurred at the following times.

Acceptability Study -	Started	October 1987
	Finished	May 1988
Efficacy Study -	Started	February 1989
	Finished	June 1990

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**Re: Reality Female Condom
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U.S. Patent No. 4,976,273
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Dear Mr. Malkin:

Please note that the applicant's attorney for the application for patent term extension has the new address and telephone number as identified above.

Sincerely yours,

Paul Grandinetti

Paul Grandinetti

PG:jt

cc: Ms. Joan Hann

Mr. Brian J. Malkin
February 16, 1994
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Collier, Shannon, Rill & Scott

Neither an IDE nor IRB approval was required for these studies. The date on which the device was first used with human subjects as part of a clinical investigation to be filed with the FDA to secure pre-market approval of the device was in October, 1987. Therefore, the applicant identifies October 31, 1987, as the most certain date upon which such a study occurred.

If additional information is required, please do not hesitate to contact us.

Sincerely yours,



Paul Grandinetti

PG:jt
cc: Ms. Joan Hann